UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	)	Criminal No. 23-cr-10094-PBS
v.	)	Violation:
REBA DAOUST,	)	Count One: False Statements (18 U.S.C. § 1001(a)(1))
Defendant.	)	

SUPERSEDING INFORMATION

The United States Attorney alleges that, at all times relevant to this Information:

General Allegations

1. Magellan Diagnostics, Inc., headquartered in Billerica, Massachusetts, was a medical device company that sold products for detecting lead levels and lead poisoning in the blood of children and adults. Those devices included, but were not limited to, LeadCare II, LeadCare Ultra, and LeadCare Plus (collectively, the "LeadCare Devices").

2. The defendant REBA DAOUST was an individual residing in Amesbury, Massachusetts. DAOUST was Magellan's Director of Quality Assurance and Regulatory Affairs from in or around 2012 through in or around July 28, 2017.

3. Amy Winslow was an individual residing in Needham Heights, Massachusetts. Winslow was Magellan's President and Chief Executive Officer from in or around 2011 through in or around 2018.

4. Hossein Maleknia was an individual residing in North Andover, Massachusetts. Maleknia was Magellan's Chief Operating Officer and Vice President of Operations from in or around 2012 through in or around 2021.

5. DAOUST, Winslow, Maleknia, and others known and unknown to the U.S. Attorney misled the United States Food and Drug Administration (FDA) about a malfunction that tended to cause the LeadCare Devices to produce inaccurate blood lead level results.

Lead Poisoning and Blood Lead Testing

6. According to the Centers for Disease Control and Prevention (CDC), there is no safe level of lead in the blood. Lead exposure may cause irreversible lifelong physical and mental health problems, including damage to the nervous, hematopoietic, endocrine, renal, and reproductive systems. Lead exposure may also damage children's ability to learn, ability to pay attention, and academic achievement. High levels of lead exposure attack the brain and central nervous system and may cause coma, convulsions, and even death.

7. Lead poisoning can be difficult to detect—signs and symptoms of lead poisoning usually do not appear until dangerously high amounts of lead have accumulated in the body. Blood lead testing is the best way to detect lead poisoning.

8. In 2012, the CDC introduced a medical threshold at blood lead levels of 5 micrograms per deciliter (μg/dL) to identify children and adults who have elevated blood lead levels. At that level, the CDC recommended that healthcare providers take a number of steps, including identifying possible causes of lead exposure, recommending ways to prevent further lead exposure, and providing follow-up blood lead testing at recommended intervals. The CDC recommended additional interventions for higher levels of lead in the blood, including the recommendation that physicians consider the need for hospitalization and chelation therapy to remove lead from the blood if the level reached 45 μg/dL.

LeadCare Devices

9. LeadCare II was released in 2006 and was the only point-of-care lead testing device, which means it was cleared by the FDA for use in non-laboratory settings such as doctors' offices and clinics. LeadCare II could be used to test blood samples drawn from a fingerstick or heelstick ("capillary" blood samples) and blood samples drawn from a vein ("venous" blood samples) but was predominantly used for capillary blood samples.

10. LeadCare Ultra was released in 2013 and was designed for use at medium and large hospitals and reference labs. LeadCare Ultra could be used to test both capillary blood samples and venous blood samples but was predominantly used for venous blood samples.

FDA and FDCA

11. The FDA was responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices—including diagnostic testing devices—were safe and effective. Under its statutory mandate, the FDA regulated the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

12. The Federal Food, Drug, and Cosmetic Act (FDCA), among other things, governed the manufacture and interstate distribution of medical devices for human use, as codified at 21 U.S.C. §§ 301 *et seq*.

13. The FDCA and its implementing regulations provided a mechanism that allowed the FDA, and others, to identify and monitor adverse events and malfunctions involving medical devices. Medical device reports (MDRs) were one of the post-market surveillance tools that the FDA used to monitor device performance and detect potential device-related safety issues.

14. Medical device manufacturers were required to submit MDRs within 30 calendar days after becoming aware of a device malfunction pursuant to 21 U.S.C. § 360i(a) and 21 CFR

Part 803 if the malfunction was likely to cause or contribute to serious injury or death if it recurred. Device malfunctions were defined as a failure of the device to perform as intended or meet its performance specifications, including all claims made in the device labeling, under 21 CFR § 803.3.

LeadCare Ultra Application for FDA Clearance and Discovery of the Malfunction

15. In or around November 2012, Magellan sought clearance from the FDA to introduce into the market its newly developed LeadCare Ultra device. Magellan submitted a premarket notification to the FDA, which claimed that LeadCare Ultra was substantially equivalent to the already-cleared LeadCare II device.

16. On or about January 14, 2013, the FDA issued a hold memo for Magellan's LeadCare Ultra submission, which noted several deficiencies and requested additional studies and documentation concerning, among other things, the operation of LeadCare Ultra within various temperature and humidity ranges.

17. While conducting the temperature and humidity studies requested by the FDA in the hold memo, Magellan discovered a malfunction affecting the LeadCare Ultra device (the "Malfunction"). The Malfunction tended to result in lower blood lead values when the blood sample was tested shortly after it was mixed with treatment reagent and higher blood lead values if the blood-treatment reagent mixture were allowed to sit, or "incubate," for several hours or days before testing.

18. The Malfunction was first observed in or around June 2013, when a Magellan employee performed the temperature and humidity studies requested by the FDA. This employee forwarded the results of this study to DAOUST, who expressed concerns over the findings.

DAOUST informed Winslow and Maleknia at least as early as June 28, 2013, about the Malfunction affecting LeadCare Ultra.

19. Magellan did not notify the FDA about the results of its temperature and humidity studies that showed the Malfunction.

20. The FDA—unaware of the Malfunction—cleared the LeadCare Ultra device for marketing and distribution on or about August 20, 2013.

Confirmation of the Malfunction and Delayed Release of LeadCare Ultra

21. Despite its original plans to do so, Magellan did not release LeadCare Ultra to the market shortly after FDA clearance because of concerns about the Malfunction.

22. From in or around August 2013 until in or around December 2013, Magellan designed and conducted multiple studies comparing LeadCare Ultra test results measured (a) immediately after blood samples were mixed with treatment reagent and (b) after allowing the blood-treatment reagent mixture to incubate for various time periods (the "2013 Malfunction Studies"). While the Malfunction did not appear in every experiment, the 2013 Malfunction Studies repeatedly showed that the Malfunction occurred when testing various types of blood samples, at various lead concentrations, and using various sensors and treatment reagents. DAOUST reviewed and discussed the results of the 2013 Malfunction Studies with Winslow and Maleknia.

23. Magellan knew that the Malfunction was likely to cause or contribute to serious injury or death if it recurred.

24. Magellan released LeadCare Ultra for sale to customers in or around December 2013. Magellan did not notify customers or the FDA in 2013 that the Malfunction could cause

false lows and false highs, especially if testing was conducted immediately after mixing blood samples with treatment reagent.

Discovery and Confirmation of the Malfunction in LeadCare II

25. During the 2013 Malfunction Studies, Magellan conducted studies to determine whether the Malfunction affected LeadCare II as well as LeadCare Ultra. Those studies confirmed that the Malfunction was not an isolated problem with LeadCare Ultra but was "a general phenomenon" that also affected LeadCare II when it was used to test venous blood samples. DAOUST was aware of these results.

26. Magellan did not notify customers or the FDA in 2013 that the Malfunction was likely to cause inaccurate test results when LeadCare II was used to test venous blood samples.

LeadCare Ultra Customer Complaints and Customer Letter

27. Beginning in or around August 2014 and continuing through in or around October 2014, certain LeadCare Ultra customers independently discovered the Malfunction after they observed inaccurate and changing lead test results. These customers reported to Magellan that they had received unexpectedly low test results—including false lows that were below the CDC's medical threshold of 5 µg/dL—when blood samples were tested immediately after being mixed with treatment reagent, and had found that the lead test result was higher if the sample was tested an hour after the sample was mixed with treatment reagent.

28. On or about November 24, 2014, Magellan sent LeadCare Ultra customers a letter about the Malfunction (the "LeadCare Ultra Customer Letter"), which was drafted by DAOUST, edited by Winslow, and approved by Maleknia. The Lead Care Ultra Customer Letter suggested that Magellan had not observed the Malfunction in 2013 prior to product launch and advised customers to allow the blood-treatment reagent mixture to sit for a minimum of 24 hours before

testing. This advice contradicted the LeadCare Ultra label, which permitted users to analyze the blood sample immediately after mixing the sample and treatment reagent.

LeadCare Ultra MDR

29. Prior to April 2015, neither DAOUST, Winslow, Maleknia, nor any other Magellan employee notified the FDA about (a) Magellan's discovery of the Malfunction or (b) Magellan's change to the LeadCare Ultra user instructions, communicated directly to customers via the LeadCare Ultra Customer Letter.

30. On or about April 2, 2015, after an outside consultant advised DAOUST and others that Magellan needed to report the Malfunction to the FDA or he would do so himself, Magellan submitted an MDR about the Malfunction, which was drafted by DAOUST (the "LeadCare Ultra MDR").

31. The LeadCare Ultra MDR drafted by DAOUST contained several materially false and misleading statements and concealed material facts about the Malfunction and Magellan's discovery of the Malfunction. For instance, the LeadCare Ultra MDR stated: "In November of [2014], we determined that blood lead results were being underestimated[.]" This statement was materially false and misleading because Magellan observed the Malfunction in the 2013 Malfunction Studies, prior to its release of LeadCare Ultra for sale to customers in or around December 2013.

32. In or around August 2015, DAOUST, Maleknia, and others approved an engineering change order that changed the LeadCare Ultra label, user guide, and website to incorporate the 24-hour incubation instruction. Neither DAOUST, Winslow, Maleknia, nor any other Magellan employee notified the FDA of the change.

Test Tube Experiments

33. In or around 2015, Magellan continued to conduct studies to identify the most likely root cause of the Malfunction, focusing on whether a substance in the rubber stopper of commonly used test tubes interfered with the LeadCare Device sensors and caused test results to be lower than expected.

34. Magellan did not notify its customers or the FDA of the results of its studies into the root cause of the Malfunction, which showed that the LeadCare Devices did not function properly when used with several types of widely available test tubes.

Notification to FDA about LeadCare II Malfunction

35. On or about November 7, 2016, DAOUST submitted an amendment to the LeadCare Ultra MDR disclosing that the Malfunction also affected LeadCare II (the "LeadCare II MDR").

36. The LeadCare II MDR and its cover letter, which was signed by DAOUST, contained materially false and misleading statements and concealed material facts about Magellan's discovery of the Malfunction in LeadCare II, including the following: "Once Magellan found out the root cause [of the Malfunction] we retested the LeadCare II which originally did not exhibit this issue." This statement was materially false and misleading because Magellan was aware that LeadCare II was affected by the Malfunction as early as in or around October and November 2013, long before it discovered the most likely root cause of the Malfunction in LeadCare Ultra.

2017 Recall

37. In or around 2017, the FDA contacted Magellan with questions about the Malfunction.

38. During a conference call held on or about April 20, 2017, an FDA representative asked when Magellan first discovered the Malfunction. Based on input from DAOUST and Maleknia before the call, and at the direction of DAOUST during the call, a regulatory consultant for Magellan falsely told the FDA that Magellan first discovered the problem in late 2014 after receiving customer complaints and shortly before the LeadCare Ultra MDR was filed. This statement was materially false and misleading because Magellan actually discovered the Malfunction in 2013.

39. The FDA ultimately found that Magellan's data showed that the LeadCare Devices could not accurately test venous blood samples, regardless of the recommended incubation times.

40. In or around May 2017, the FDA recommended a recall of all LeadCare Devices using venous blood samples and warned the public not to use the devices for venous blood samples because of the Malfunction.

COUNT ONE
False Statements
(18 U.S.C. § 1001(a)(1))

The United States Attorney charges:

41. The United States Attorney re-alleges and incorporates by reference paragraphs 1 through 40 of this Information.

42. From in or around December 2013 through in or around May 2017, within the District of Massachusetts and elsewhere, the defendant,

REBA DAOUST,

did knowingly and willfully falsify, conceal, and cover up by trick, scheme, and device a material fact in a matter within the jurisdiction of the executive branch of the government of the United States, that is, the FDA, in that the defendant, in the April 2015 LeadCare Ultra MDR, the November 2016 LeadCare II MDR, and the April 2017 call with the FDA, concealed the fact that Magellan discovered the Malfunction in 2013.

All in violation of Title 18, United States Code, Section 1001(a)(1).

LEAH B. FOLEY
United States Attorney
District of Massachusetts

KELLY BEGG LAWRENCE
JAMES D. HERBERT
LESLIE A. WRIGHT
Assistant United States Attorneys
District of Massachusetts

February 26, 2025